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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,922	08/05/2002	Albert B. Deisseroth	044574-5059-US	6375
28977	7590	07/01/2004	EXAMINER	
MORGAN, LEWIS & BOCKIUS LLP 1701 MARKET STREET PHILADELPHIA, PA 19103-2921			PRIEBE, SCOTT DAVID	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/856,922

Applicant(s)

DEISSEROTH, ALBERT B.

Examiner

Scott D. Priebe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4, 6-10, 29 and 30, drawn to a conditionally replication competent adenoviral vector comprising a plastin promoter operably linked to the adenoviral E1 gene.

Group II, claim(s) 1-12, 14, 29 and 30, drawn to a vector comprising a plastin promoter operably linked to a gene encoding a thymidine kinase.

Group III, claim(s) 1-13, 29 and 30, drawn to a vector comprising a plastin promoter operably linked to a gene encoding a cytosine deaminase, and optionally also an OPRase.

Group IV, claim(s) 1-12, 15, 29 and 30, drawn to a vector comprising a plastin promoter operably linked to a gene encoding a purine nucleotide phosphorylase.

Group V, claim(s) 1-12, 16, 29 and 30, drawn to a vector comprising a plastin promoter operably linked to a gene encoding a nitroreductase.

Group VI, claim(s) 1-12, 29 and 30, drawn to a vector comprising a plastin promoter operably linked to a gene encoding a  $\beta$ -galactosidase.

Group VII, claim(s) 1-12, 17, 29 and 30, drawn to a vector comprising a plastin promoter operably linked to a gene encoding a cytochrome P450 reductase.

Group VIII, claim(s) 1-12, 18, 29 and 30, drawn to a vector comprising a plastin promoter operably linked to a gene encoding a deoxycytidine kinase.

Group IX, claim(s) 1-12, 29 and 30, drawn to a vector comprising a plastin promoter operably linked to a gene encoding a carboxylesterase.

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Group X, claim(s) 1-12, 19, 29 and 30, drawn to a vector comprising a plastin promoter operably linked to a gene encoding a thymidine phosphorylase.

Group XI, claim(s) 20, 21, 25, 26 and 28, drawn to a method of sensitizing a tumor cell by transfection with a vector comprising a plastin promoter operably linked to a gene encoding a thymidine kinase.

Group XII, claim(s) 20, 21, and 25-28, drawn to a method of sensitizing a tumor cell by transfection with a vector comprising a plastin promoter operably linked to a gene encoding a cytosine deaminase.

Group XIII, claim(s) 20, 21, 25, 26 and 28, drawn to a method of sensitizing a tumor cell by transfection with a vector comprising a plastin promoter operably linked to a gene encoding a purine nucleotide phosphorylase.

Group XIV, claim(s) 20, 21, 25, 26 and 28, drawn to a method of sensitizing a tumor cell by transfection with a vector comprising a plastin promoter operably linked to a gene encoding a nitroreductase.

Group XV, claim(s) 20, 21, 25, 26 and 28, drawn to a method of sensitizing a tumor cell by transfection with a vector comprising a plastin promoter operably linked to a gene encoding a  $\beta$ -galactosidase.

Group XVI, claim(s) 20, 21, 25, 26 and 28, drawn to a method of sensitizing a tumor cell by transfection with a vector comprising a plastin promoter operably linked to a gene encoding a cytochrome P450 reductase.

Group XVII, claim(s) 20, 21, 25, 26 and 28, drawn to a method of sensitizing a tumor cell by transfection with a vector comprising a plastin promoter operably linked to a gene encoding a deoxycytidine kinase.

Group XVIII, claim(s) 20, 21, 25, 26 and 28, drawn to a method of sensitizing a tumor cell by transfection with a vector comprising a plastin promoter operably linked to a gene encoding a carboxylesterase.

Group XIX, claim(s) 20, 21, 25, 26 and 28, drawn to a method of sensitizing a tumor cell by transfection with a vector comprising a plastin promoter operably linked to a gene encoding a thymidine phosphorylase.

Group XX, claim(s) 22-26 and 28, drawn to a method for removing tumor cells from a sample of bone marrow or peripheral blood mononuclear cells by transfection with a vector comprising a plastin promoter operably linked to a gene encoding a thymidine kinase.

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Group XXI, claim(s) 22-28, drawn to a method for removing tumor cells from a sample of bone marrow or peripheral blood mononuclear cells by transfection with a vector comprising a plastin promoter operably linked to a gene encoding a cytosine deaminase.

Group XXII, claim(s) 22-26 and 28, drawn to a method for removing tumor cells from a sample of bone marrow or peripheral blood mononuclear cells by transfection with a vector comprising a plastin promoter operably linked to a gene encoding a purine nucleotide phosphorylase.

Group XXIII, claim(s) 22-26 and 28, drawn to a method for removing tumor cells from a sample of bone marrow or peripheral blood mononuclear cells by transfection with a vector comprising a plastin promoter operably linked to a gene encoding a nitroreductase.

Group XXIV, claim(s) 22-26 and 28, drawn to a method for removing tumor cells from a sample of bone marrow or peripheral blood mononuclear cells by transfection with a vector comprising a plastin promoter operably linked to a gene encoding a  $\beta$ -galactosidase.

Group XXV, claim(s) 22-26 and 28, drawn to a method for removing tumor cells from a sample of bone marrow or peripheral blood mononuclear cells by transfection with a vector comprising a plastin promoter operably linked to a gene encoding a cytochrome P450 reductase.

Group XXVI, claim(s) 22-26 and 28, drawn to a method for removing tumor cells from a sample of bone marrow or peripheral blood mononuclear cells by transfection with a vector comprising a plastin promoter operably linked to a gene encoding a deoxycytidine kinase.

Group XXVII, claim(s) 22-26 and 28, drawn to a method for removing tumor cells from a sample of bone marrow or peripheral blood mononuclear cells by transfection with a vector comprising a plastin promoter operably linked to a gene encoding a carboxylesterase.

Group XXVIII, claim(s) 22-26 and 28, drawn to a method for removing tumor cells from a sample of bone marrow or peripheral blood mononuclear cells by transfection with a vector comprising a plastin promoter operably linked to a gene encoding a thymidine phosphorylase.

The inventions listed as Groups I-XXVIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature shared by groups I-X or by groups XI-XIX or by groups XX-XXVIII is the use of a plastin promoter to drive expression of a gene. However, this technical feature is not a special technical feature since WO 94/17182 disclosed vectors comprising a

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plastin promoter operably linked to a gene whose induction modifies the metabolism of a cell, such as a gene encoding a toxin for killing of certain types of cancer cells in which the plastin promoter is active (pages 20-22, or claim 14, for example). The products of group I are not required for, and thus share no special technical feature with, the methods of groups XI-XXVIII. As admitted in the specification (pages 9-10), the various GDEPT systems represented in groups II-X, XI-XIX, and XX-XXVIII, respectively, were known in the art for use in killing tumor cells, and would be obvious for use in conjunction with a plastin promoter in view of the teachings of WO 94/17182, and thus do not constitute a special technical feature that links the products of groups II-X with the methods of XI-XIX or XX-XXVIII, respectively.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection

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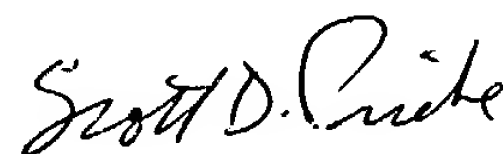
are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy J. Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Scott D. Priebe  
Primary Examiner  
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